National Center for Toxicological Research (NCTR).

(2) The Director and Deputy Directors for Science and for Regulations and Policy, Centers for Devices and Radiological Health (CDRH).

(3) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(5) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(6) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC).

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii).

(c) The Senior Associate Commissioner for Management and Systems, Office of Management and Systems (OMS), OC; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services (OFACS), OMS, OC; the Director, Division of Contracts and Procurement Management (DCPM), OFACS, OMS, OC; and the Chief Grants Management Officer and the Grants Management Officer, DCPM, OFACS, OMS, OC are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director, NCTR, is authorized under section 301 of the PHS Act (42 U.S.C. 241), as amended by Public Law 95–622, to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center that are not required to support Center research programs.

(e) The Senior Associate Commissioner for Management and Systems may further redelegate the authorities in paragraph (c) of this section. With the exception for paragraph (c) of this section, these officials may not further redelegate these authorities.

§ 5.26 Service fellowships.

(a) Under authority of sections 207(g) and 208(f) of the PHS Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for individual actions within the ranges established under an approved service fellowship plan:

(1) The Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Chief Counsel and Deputy Chief Counsels; and the Associate Commissioners and their Deputies.

(2) The Director, the Deputy Director for Washington Operations, the Deputy Center Directors for Research and Management, respectively, and the Associate Director, Office of Management Services, National Center for Toxicological Research (NCTR).

(3) The Director, the Deputy Directors for Science and for Regulations and Policy, and the Director, Office of Systems and Management, Center for Devices and Radiological Health (CDRH).

(4) The Director, the Deputy Directors, the Associate Director for Research, the Office Directors, and the Director, Office of Management, Center for Biologics Evaluation and Research (CBER).

(5) The Director, the Deputy Director, and Director, Office of Management Systems, Center for Food Safety and Applied Nutrition (CFSAN).

(6) The Director, the Deputy Director, and the Director, Office of Management and Communications, Center for Veterinary Medicine (CVM).

(7) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, and the Director and Deputy Director, Office of Management, Center for Drug Evaluation and Research (CDER).

(8) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner and the Director, Office of Resource Management, ORA.

(9) Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(b) These officials may further redelegate this authority, with the limitation that the Director, Office of Human Resources and Management Services, OMS, OC, is delegated the authority to approve service fellowship plans and exceptions to the approved plans, and this official may not further redelegate this authority.

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.

(a) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under section 156(d)(2)(B)(ii) of title 35 U.S.C. (35 U.S.C. 156), as amended, relative to patent term extensions.

(b) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Regulatory Policy, CDER, are authorized to perform the functions delegated to the Commissioner under title 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under title 35 U.S.C. 156(d)(2)(B).

(c) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under title 35 U.S.C. 156 (d)(2)(B), as amended, except for holding of informal hearings under title 35 U.S.C. 156(d)(2)(B)(ii).

(d) These officials may not further redelegate this authority.

§ 5.28 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335, 344(b), and 381(a)); section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) (21 U.S.C. 145); section 9(b) of the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19 formerly section 18); and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.